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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/578,908 05/26/00 MESENS

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COVINGTON & BURLING  
ATTN: PATENT DOCKETING  
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EXAMINER

SACKY, F.

ART UNIT

PAPER NUMBER

1626

DATE MAILED:

08/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/578,908

Applicant(s)

MESENS ET AL.

Examiner

EBENEZER SACKKEY

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1626



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) ☒ Responsive to communication(s) filed on Jun 18, 2001.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4) ☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above, claim(s) 2, 4, 6, 8, 10, 12, 14, 16, 18, and 20-28 is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1, 3, 5, 7, 9, 11, 13, 17, and 19 is/are rejected.

7) ☒ Claim(s) 15 is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other:

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## **DETAILED ACTION**

Claims 1-28 are pending.

### ***Response to Restriction***

Applicant's election with traverse of Group I in Paper No. 8 is acknowledged. The traversal is on the ground(s) that independent claims 1 and 2 and claims 3-20 should be examined together because the claims depend directly or indirectly therefrom the use of micro particles having both a biodegradable and biocompatible polymer and respridone. This is not found persuasive because independent claim 2, (Group II) comprises biocompatible polymeric matrix which falls into a different statutory class. Moreover, the two groups are capable of supporting their own patents. Therefore, examining the two Groups would be burdensome.

The requirement is still deemed proper and is therefore made FINAL.

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***Claim Rejections - 35 U.S.C. § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of psychotic disorders, does not reasonably provide enablement for the extraction of micro particles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The above claim recite a method of treating warm blooded animals suffering from psychotic disorders with a composition of a biodegradable and biocompatible polymer, risperidone, 9-hydroxy-risperidone and a pharmaceutically acceptable acid salt. The claim further recite the extraction of solvent to form micro particles. Therefore, one of ordinary skill is left to speculate as to the intent of the claims.

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3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 7, 9, 11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the extraction of micro particles and subsequent injection intra-dermally. At best such would raise the issue of safety because the extraction of the "solvent" to produce the micro particles means dry "powder" is being administered. This may lead to sepsis and formation of other tumors to say the least.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*,

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422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 3, 5, 7, 9, 11, 13, 17 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,770,231. Although the conflicting claims are not identical, they are not patentably distinct from each other because the sustained -released micro particles of '231' and the instant claims are similar. Moreover, the composition of the micro particle are also similar, namely, a biodegradable and biocompatible polymer to from an organic phase, active agent selected from risperidone, 9-hydroxy-risperidone and a pharmaceutically acceptable acid addition salts.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone

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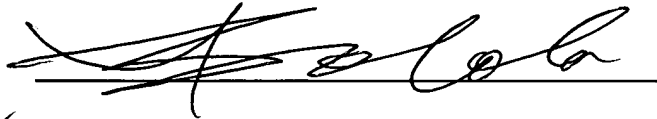
number is (703) 305-6889. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

EOS

July 30, 2001.

*for*   
Joseph K. McKane

Supervisory Patent Examiner

Art Unit 1626, Group 1600

Technology Center 1

*T-A Solola*